

3/10/06

PTO/SB/08 Equivalent

## INFORMATION DISCLOSURE

## STATEMENT BY APPLICANT

(Multiple sheets used when necessary)

SHEET 1 OF 2

Application No. 10/518,223

Filing Date December 15, 2004

First Named Inventor Ning Man Cheng

Art Unit 1652

Examiner Iqbal Hossain Chowdhury

Attorney Docket No. EAGIP5.001APC

## U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
IC	1	6,261,557 B1	07-17-2001	Tepic, et al.	
IC	2	6,316,199 B1	11-13-2001	Vockley, et al.	

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T <sup>1</sup>
IC	3	EP 0 956 864 A1	11-17-1999	Kyowa Hakko Kogyo Co., Ltd.		
IC	4	WO 98/06421	02-19-1998	Cancer Treatments International		
IC	5	WO 99/43345 A1	09-02-1999	Eisai Co., Ltd.		
IC	6	WO 02/09766 A1	02-07-2002	Park, et al.		
IC	7	WO 02/024156 A3	03-28-2002	Henkel Kommanditgesellschaft Auf Aktien		
IC	8	WO 02/44360 A2	06-06-2002	Phoenix Pharmacologics, Inc.		
IC	9	WO 2003/063780 A3	08-07-2003	Cancer Treatments International		

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>1</sup>
IC	10	Baillie, et al. 1998. A heat-inducible <i>Bacillus subtilis</i> bacteriophage $\Phi$ 105 expression system for the production of the protective antigen of <i>Bacillus anthracis</i> . <i>FEMS Microbiology Letters</i> , 163:43-47.	
IC	11	Colleluori, et al. 2001. Expression, purification, and characterization of human type II arginase. <i>Archives of Biochemistry and Biophysics</i> , 389(1):135-143.	
IC	12	Haraguchi, et al. Created June 7, 1987; last updated, Version 5, March 4, 2000. Molecular cloning and nucleotide sequence of cDNA for human liver arginase. Database accession no. M14502, abstract. XP-002258160.	
IC	13	Haraguchi, et al. 1987. Molecular cloning and nucleotide sequence of cDNA for human liver arginase. <i>Proc. Natl. Acad. Sci. USA</i> . 84:412-415.	
IC	14	Harris, et al. Pegylation: A novel process for modifying pharmacokinetics. <i>Clin. Pharmacokinet</i> , 40:539-551.	

Examiner Signature /Iqbal Chowdhury/ (08/02/2006)

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Application No.	10/518,223
Filing Date	December 15, 2004
First Named Inventor	Ning Man Cheng
Art Unit	1652
Examiner	Iqbal Hossain Chowdhury
Attorney Docket No.	EAGIP5.001APC

(Multiple sheets used when necessary)

SHEET 2 OF 2

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials	No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>1</sup>
IC	15	Ikemoto, et al. 1989. Purification and properties of human erythrocyte arginase. <i>Ann. Clin. Biochem.</i> , 26:547-553.	
	16	Ikemoto, et al. 1990. Expression of human liver arginase in <i>Escherichia coli</i> . <i>Biochem. J.</i> , 270:697-703.	
	17	Lamb, et al. 2000. Single amino acid (arginine) deprivation induces G1 arrest associated with inhibition of Cdk4 expression in cultured human diploid fibroblasts. <i>Experimental Cell Research</i> , 255:238-249.	
	18	Lea, et al. 1993. Inhibitory effect of arginine restriction on hepatoma growth. <i>Cancer Biochem. Biophys.</i> , 13(3):171-179.	
	19	Leung, et al. 1995. Characterization of an insertion in the phage $\Phi$ 105 genome that blocks host <i>Bacillus subtilis</i> lysis and provides strong expression of heterologous genes. <i>Gene</i> , 154:1-6.	
	20	Malumbres, et al. 2001. To cycle or not to cycle: A critical decision in cancer. <i>Nature Reviews</i> , 1:222-231.	
	21	Ozer, N. 1985. A new enzyme-coupled spectrophotometric method for the determination of arginase activity. <i>Biochemical Medicine</i> , 33:367-371.	
	22	Savoca, et al. 1979. Preparation of a non-immunogenic arginase by the covalent attachment of polyethylene glycol. <i>Biochimica et Biophysica Acta.</i> , 578:47-53.	
	23	Savoca, et al. 1984. Cancer therapy with chemically modified enzymes. II. The therapeutic effectiveness of arginase, and arginase modified by the covalent attachment of polyethylene glycol, on the taper liver tumor and the L5178Y murine leukemia. <i>Cancer Biochem Biophys.</i> , 7:261-268.	
	24	Scott, et al. 2000. Single amino acid (arginine) deprivation: Rapid and selective death of cultured transformed and malignant cells. <i>British Journal of Cancer</i> , 83(6):800-810.	
	25	Storr, et al. 1974. The effects of arginine deficiency on lymphoma cells. <i>British Journal of Cancer</i> , 30:50-59.	
	26	Thornewell, et al. 1993. An efficient expression and secretion system based on <i>Bacillus subtilis</i> phage $\Phi$ 105 and its use for the production of <i>B. cereus</i> $\beta$ -lactamase I. <i>Gene</i> , 133:47-53.	
	27	Wheatley, et al. 2000. Single amino acid (arginine) restriction: Growth and death of cultured HeLa and human diploid fibroblasts. <i>Cellular Physiology and Biochemistry</i> , 10:37-55.	
	28	Examination Report from New Zealand Patent Application No. 537774 dated March 11, 2005.	
↓	29	International Preliminary Examination Report from PCT/GB03/02665 dated July 20, 2004.	
IC	30	Written Opinion from PCT/GB03/02665 dated March 22, 2004.	

2421006:dmb  
030606

Examiner Signature /Iqbal Chowdhury/ (08/02/2006)

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.

7/14/06

IDS - 07/14/2006

PTO/SB/08B (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>		<b>Complete If Known</b>	
		Application Number	US10/518,223
		Filing Date	15 December 2004
		First Named Inventor	Paul N M Cheng
		Art Unit	1652
		Examiner Name	Iqbal Chowdhury
Sheet 1	of 1	Attorney Docket Number B001.001.NPRUS	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
IC	1	Ikemoto et al., Live-type Arginase is a Highly Sensitive Marker for Hepatocellular Damage in Rats, Clinical Chemistry, 2001, p.496-498, Vol 47	

Examiner Signature	/Iqbal Chowdhury/ (08/02/2006)	Date Considered	
--------------------	--------------------------------	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.